FDA-Industry GDUFA Reauthorization Meeting
October 21, 2015, 10:00 am - 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1219

Purpose

To identify and describe problems in GDUFA I in order to lay the groundwork for proposing effective solutions in GDUFA II.

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Ashley Boam	CDER	Kiran Krishnan	GPhA (Apotex)
Mary Beth Clarke	CDER	Marcie McClintic Coates	GPhA (Mylan)
Keith Flanagan	CDER	Molly Rapp	GPhA (Frensius-Kabi)
Robert Lionberger	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA (Catalent)
Edward Sherwood	CDER	Elizabeth Stampa	EFCG (Medichem)
Martin Shimer	CDER	Tom Thorpe	PBOA (Afton Scientific)
		Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff

Carter Beach, Heather Brown, Deborah Elliott, Derek Griffing, Michael Jones, Michael Neuenschwander, Martha Nguyen, Donal Parks, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

Industry Supporting Staff

Lisa Tan (GPhA), Mark Hendrickson (GPhA)

Discussion

Industry confirmed that it agreed with the negotiation ground rules that FDA presented at the first negotiation meeting on October 7, 2015. Industry also agreed with FDA's proposal to have a small business workgroup.

FDA discussed two fundamental issues with GDUFA I. First, FDA explained that the overly complex metric review goals are difficult to operationalize, delinked from FDA's public health goals and its other GDUFA commitments, and not in line with stakeholders' expectations. Second, FDA stated that the current underdeveloped pre-ANDA process leads to more work after an ANDA is submitted, which often results in additional review cycles. FDA also discussed other areas where there are opportunities to address certain challenges in GDUFA I, including: Drug Master Files (DMFs); the Inactive Ingredient Database (IID); and communications transparency.

Industry discussed the reasons it participated in negotiating GDUFA I. Industry explained that it hopes to leverage lessons learned from GDUFA I to support a successful GDUFA II. Industry identified the following priority areas that it hopes to explore more thoroughly at future negotiation meetings:

1. Enhanced accountability requirements
2. Controlled correspondence
3. Transparency and increased communication practices
4. Enhanced use of IT to improve communication/transparency with industry
5. GDUFA funding/fees
6. FDA financial and performance reporting
7. Compliance evaluation/inspections
8. Regulatory sciences
9. Creation of a specialized review pathway for complex abbreviated new drug application
10. Small business consideration
11. Enhanced public relations efforts

Finally, FDA discussed having a separate review track for priority ANDAs as compared to standard ANDAs. FDA explained that this would be more in line with its public health goals and the expectations of a wide range of stakeholders. Industry indicated that it also had ideas for review goals, and that Industry looks forward to further discussing this topic with FDA at future negotiation meetings.

Next Meeting
The next negotiation meeting is planned for Thursday, November 5, 2015.